

UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF NEW YORK

-----X

JONATHAN SOLLIS,

Plaintiff,

-against-

ASTRAZENECA PHARMACEUTICALS LP;  
ASTRAZENECA LP; ASTRA USA INC.; KBI SUB  
INC.; ZENECA INC.; ASTRA USA HOLDINGS  
CORPORATION; ASTRAZENECA, AB;  
ASTRAZENECA, PLC; ASTRAZENECA, UK  
LIMITED; PROCTER & GAMBLE COMPANY;  
PROCTER & GAMBLE PHARMACEUTICALS  
INC.; and PROCTER & GAMBLE  
MANUFACTURING COMPANY.

Defendants.

-----X

**COMPLAINT**

**JURY TRIAL**  
**DEMANDED**

**ECF CASE**

Plaintiff, by Plaintiff's attorneys, Kenneth E. Belkin, Esq. and Peter N. Smith, Esq. upon information and belief, at all times hereinafter mentioned, alleges as follows:

**PRELIMINARY STATEMENT**

1. This action is brought on behalf of Plaintiff, JONATHAN SOLLIS, who used Prilosec for treatment of peptic disorders which include gastroesophageal reflux disease (GERD), peptic ulcer disease, and nonsteroidal anti-inflammatory drug induced gastropathy.

2. Plaintiff seeks compensatory damages as a result of Plaintiff's use of Prilosec, which has caused Plaintiff to suffer from Chronic Kidney Disease, Renal Cell Carcinoma, surgery to remove a large tumor from his kidney, loss of 15% of kidney, internal bleeding, surgery to repair his internal bleeding, a painful hernia caused by the cancer removal, additional surgeries to repair the hernia, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above named health consequences.

Defendants, AstraZeneca Pharmaceuticals LP, AstraZeneca LP, Astra USA Inc., Kbi Sub Inc., Zeneca Inc., Astra USA Holdings Corporation, AstraZeneca, AB, AstraZeneca, PLC, and AstraZeneca, UK Limited,(hereinafter collectively referred to as "Defendants") designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed Prilosec. When warning of safety and risks of Prilosec, Defendants negligently represented to the medical and healthcare community, the Food and Drug Administration (hereinafter referred to as the "FDA"), to Plaintiff and the public in general, that Prilosec had been tested and was found to be safe and/or effective for its indicated use.

3. Defendants concealed their knowledge of Prilosec's defects from Plaintiff, the FDA, the public in general and/or the medical community specifically.
4. Defendants made these representations with the intent of defrauding and deceiving Plaintiff, the public in general, and the medical and healthcare community in particular, and were made with the intent of inducing the public in general, and the medical community in particular, to recommend, dispense and/or purchase Prilosec for the

treatment of peptic disorders which include gastroesophageal reflux disease (GERD), peptic ulcer disease, and nonsteroidal anti-inflammatory drug induced gastropathy, all of which evinced a callous, reckless, willful, depraved indifference to health, safety and welfare of the Plaintiff herein.

5. As a result of the foregoing acts and omissions, the Plaintiff was and still is caused to suffer serious and dangerous side effects including inter alia life-threatening kidney injuries, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above named health consequences. Plaintiff herein has sustained these health consequences due to Plaintiff's use of Prilosec.
6. Defendants concealed their knowledge of the defects in their products from the Plaintiff, and Plaintiff's physicians, hospitals, pharmacists, the FDA, and the public in general and from Plaintiff SOLLIS, specifically.
7. Plaintiff seeks compensatory damages, as well as punitive damages, as a result of Plaintiff's use of Prilosec, which has caused Plaintiff to suffer from Chronic Kidney Disease (CKD) and Renal Cell Carcinoma (RCC), as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above named health consequences.

**PARTY PLAINTIFF**

8. Plaintiff, JONATHAN SOLLIS, is a citizen of the United States of America, and is a resident of New York County, New York.
9. Plaintiff, JONATHAN SOLLIS, was born on [REDACTED].
10. Plaintiff, JONATHAN SOLLIS, first began using Prilosec in or about 2006, and used Prilosec up through 2020.
11. As a result of using Defendants' Prilosec, Plaintiff JONATHAN SOLLIS, was caused to suffer CKD and RCC after taking Prilosec, and was caused to sustain severe and permanent personal injuries, pain, suffering, and emotional distress.
12. The injuries and damages sustained by Plaintiff, JONATHAN SOLLIS, were caused by Defendants' pharmaceutical drug known as Prilosec.

**PARTY DEFENDANTS**

13. Defendant AstraZeneca Pharmaceuticals LP is, and at all times relevant to this action was, a Delaware corporation with its corporate headquarters in Wilmington, Delaware.
14. At all times relevant hereto, Defendant AstraZeneca Pharmaceuticals LP was engaged in the business of designing, developing, manufacturing, testing, packaging, promoting, marketing, distributing, labeling, and/or selling Prilosec products.
15. Upon information and belief, at all relevant times, Defendant AstraZeneca Pharmaceuticals LP was present and doing business in the State of Delaware and New York.

16. Upon information and belief, at all relevant times, Defendant AstraZeneca Pharmaceuticals LP transacted, solicited, and conducted business in the States of Delaware and New York and derived substantial revenue from such business.
17. Upon information and belief, at all times relevant hereto, Defendant AstraZeneca Pharmaceuticals LP expected or should have expected that its acts would have consequences within the United States of America, and the States of Delaware and New York.
18. Defendant Astra USA Inc. is, and at all times relevant to this action was, a Delaware corporation with its corporate headquarters in Wilmington, Delaware.
19. At all times relevant hereto, Defendant Astra USA Inc. was engaged in the business of designing, developing, manufacturing, testing, packaging, promoting, marketing, distributing, labelling and/or selling Prilosec products.
20. Upon information and belief, at all relevant times, Defendant Astra USA Inc., was present and doing business in the States of Delaware and New York.
21. Upon information and belief, at all relevant times, Defendant Astra USA Inc. transacted, solicited, and conducted business in the States of Delaware and New York and derived substantial revenue from such business.
22. Defendant KBI SUB Inc. is, and at all times relevant to this action was, a Delaware corporation with its corporate headquarters in Wilmington, Delaware.
23. At all times relevant hereto, Defendant KBI SUB Inc. was engaged in the business of designing, developing, manufacturing, testing, packaging, promoting, marketing, distributing, labeling, and/or selling Prilosec products.

24. Upon information and belief, at all relevant times, Defendant KBI SUB Inc. was present and doing business in the States of Delaware and New York.

25. Upon information and belief, at all relevant times, Defendant KBI SUB Inc. transacted, solicited, and conducted business in the States of Delaware and New York and derived substantial revenue from such business.

26. Defendant Zeneca Inc. is, and at all times relevant to this action was, a Delaware corporation with its corporate headquarters in Wilmington, Delaware.

27. At all times relevant hereto, Defendant Zeneca Inc. was engaged in the business of designing, developing, manufacturing, testing, packaging, promoting, marketing, distributing, labeling, and/or selling Prilosec products.

28. Upon information and belief, at all relevant times, Defendant Zeneca Inc. was present and doing business in the States of Delaware and New York.

29. Upon information and belief, at all relevant times, Defendant Zeneca Inc. transacted, solicited, and conducted business in the States of Delaware and New York and derived substantial revenue from such business.

30. Defendant Astra USA Holding Corporation, is, and at all times relevant to this action was, a Delaware corporation with its corporate headquarters in Wilmington, Delaware.

31. At all times relevant hereto, Defendant Astra USA Holdings Corporation was engaged in the business of designing, developing, manufacturing, testing, packaging, promoting, marketing, distributing, labeling, and/or selling Prilosec products.

32. Upon information and belief, at all relevant times, Defendant Astra USA Holdings Corporation was present and doing business in the States of Delaware and New York.

33. Upon information and belief, at all relevant times, Defendant Astra USA Holdings Corporation transacted, solicited, and conducted business in the States of Delaware and New York and derived substantial revenue from such business.
34. Defendant AstraZeneca AB is, and at all times relevant to this action was, a Delaware corporation with its corporate headquarters in Wilmington, Delaware.
35. At all times relevant hereto, Defendant AstraZeneca AB was engaged in the business of designing, developing, manufacturing, testing, packaging, promoting, marketing, distributing, labeling, and/or selling Prilosec products.
36. Upon information and belief, at all relevant times, Defendant AstraZeneca AB was present and doing business in the States of Delaware and New York.
37. Upon information and belief, at all relevant times, Defendant AstraZeneca AB transacted, solicited, and conducted business in the States of Delaware and New York and derived substantial revenue from such business.
38. Defendant AstraZeneca, PLC is, and at all times relevant to this action was, a Delaware corporation with its corporate headquarters in Wilmington, Delaware.
39. At all times relevant hereto, Defendant AstraZeneca PLC was engaged in the business of designing, developing, manufacturing, testing, packaging, promoting, marketing, distributing, labeling, and/or selling Prilosec products.
40. Upon information and belief, at all relevant times, Defendant AstraZeneca PLC was present and doing business in the States of Delaware and New York.
41. Upon information and belief, at all relevant times, Defendant AstraZeneca PLC transacted, solicited, and conducted business in the States of Delaware and New York and derived substantial revenue from such business.

42. Defendant AstraZeneca UK Limited is, and at all times relevant to this action was, a Delaware corporation with its corporate headquarters in Wilmington, Delaware.
43. At all times relevant hereto, Defendant AstraZeneca UK Limited was engaged in the business of designing, developing, manufacturing, testing, packaging, promoting, marketing, distributing, labeling, and/or selling Prilosec products.
44. Upon information and belief, at all relevant times, Defendant AstraZeneca UK Limited was present and doing business in the States of Delaware and New York.
45. Upon information and belief, at all relevant times, Defendant AstraZeneca UK Limited transacted, solicited, and conducted business in the State of Delaware and New York and derived substantial revenue from such business.
46. Upon information and belief, Defendant AstraZeneca LP is, and at all times relevant to this action was, a Delaware corporation. Defendant AstraZeneca LP is the holder of approved New Drug Applications (“NDAs”) 22-056, 19-810/S-74 and 21-229 etc. for Prilosec (Omeprazole Magnesium), and it manufactures and markets Prilosec (Omeprazole Magnesium) in the United States.
47. Upon information and belief, at all times relevant hereto Defendant AstraZeneca LP was engaged in the business of designing, developing, manufacturing, testing, packaging, promoting, marketing, distributing, labeling and/or selling Prilosec Products.
48. Upon information and belief, at all relevant times, Defendant AstraZeneca LP was present and doing business in the State of Delaware and New York.
49. Upon information and belief, at all relevant times, Defendant AstraZeneca LP transacted, solicited, and conducted business in the State of Delaware and New York, and derived substantial revenue from such business.



50. Upon information and belief, at all times relevant hereto, Defendant AstraZeneca LP expected or should have expected that its acts would have consequences within the United States of America, and the State of Delaware and New York.
51. Defendant PROCTER & GAMBLE COMPANY is, and at all times relevant to this action was, an Ohio corporation with its corporate headquarters in Cincinnati, Ohio.
52. At all times relevant hereto, Defendant PROCTER & GAMBLE COMPANY was engaged in the business of designing, developing, manufacturing, testing, packaging, promoting, marketing, distributing, labeling, and/or selling Prilosec OTC products.
53. Upon information and belief, at all relevant times, Defendant PROCTER & GAMBLE COMPANY was present and doing business in the State of Delaware and New York.
54. Upon information and belief, at all relevant times, Defendant PROCTER & GAMBLE COMPANY transacted, solicited, and conducted business in the States of Delaware and New York and derived substantial revenue from such business.
55. Upon information and belief, at all times relevant hereto, Defendant PROCTER & GAMBLE COMPANY expected or should have expected that its acts would have consequences within the United States of America, and the States of Delaware and New York.
56. Defendant PROCTER & GAMBLE PHARMACEUTICALS INC. is, and at all times relevant to this action was, an Ohio corporation with its corporate headquarters in Cincinnati, Ohio.
57. At all times relevant hereto, Defendant PROCTER & GAMBLE PHARMACEUTICALS INC. was engaged in the business of designing, developing, manufacturing, testing,

packaging, promoting, marketing, distributing, labeling, and/or selling Prilosec OTC products.

58. Upon information and belief, at all relevant times, Defendant PROCTER & GAMBLE PHARMACEUTICALS INC. was present and doing business in the State of Delaware and New York.

59. Upon information and belief, at all relevant times, Defendant PROCTER & GAMBLE PHARMACEUTICALS INC. transacted, solicited, and conducted business in the States of Delaware and New York and derived substantial revenue from such business.

60. Upon information and belief, at all times relevant hereto, Defendant PROCTER & GAMBLE PHARMACEUTICALS INC. expected or should have expected that its acts would have consequences within the United States of America, and the States of Delaware and New York.

61. At all times relevant hereto, Defendant PROCTER & GAMBLE MANUFACTURING COMPANY was engaged in the business of designing, developing, manufacturing, testing, packaging, promoting, marketing, distributing, labeling, and/or selling Prilosec OTC products.

62. Upon information and belief, at all relevant times, Defendant PROCTER & GAMBLE MANUFACTURING COMPANY was present and doing business in the State of Delaware and New York.

63. Upon information and belief, at all relevant times, Defendant PROCTER & GAMBLE MANUFACTURING COMPANY transacted, solicited, and conducted business in the States of Delaware and New York and derived substantial revenue from such business.

64. Upon information and belief, at all times relevant hereto, Defendant PROCTER & GAMBLE MANUFACTURING COMPANY expected or should have expected that its acts would have consequences within the United States of America, and the States of Delaware and New York.
65. Defendants Procter & Gamble Manufacturing Company, The Procter & Gamble Company, and Procter & Gamble Pharmaceuticals Inc. are the holders of approved New Drug Application ("NDA") 021229 for Prilosec OTC (Omeprazole Magnesium), and it manufactures and markets Prilosec OTC (Omeprazole Magnesium) in the United States.
66. Upon information and belief, Defendants AstraZeneca LP; AstraZeneca Pharmaceuticals LP; AstraZeneca LP; Astra USA Inc.; KBI SUB Inc.; Zeneca Inc.; Astra USA Holdings Corporation; AstraZeneca, AB ; AstraZeneca, PLC; AstraZeneca UK Limited; Procter & Gamble Company; Procter & Gamble Pharmaceuticals Inc.; and Procter & Gamble Manufacturing Company, shall herein be collectively referred to as "Defendants."
67. Upon information and belief, each Defendant was the agent and employee of each other Defendant, and in doing the things alleged was acting within the course and scope of such agency and employment and with each other Defendant's actual and implied permission, consent, authorization, and approval.

#### **FACTUAL BACKGROUND**

68. Proton pump inhibitors ("PPI") are one of the most commonly prescribed medications in the United States and rarely unprescribed, leading to usage well past any length of time anticipated by the FDA.

69. More than 15 million Americans used prescription PPIs in 2013, generating more than \$10 billion in revenue.
70. It has been estimated that between 53% and 69% of these prescriptions have no appropriate indication<sup>1</sup>.
71. Furthermore, 25% of long-term PPI users could discontinue therapy without developing any symptoms.
72. AstraZeneca sold Prilosec with National Drug Code (NDC) numbers 00186-0606; 00186-0610; 00186-0625; 00186-0742 and 00186-0743.
73. Prilosec (Omeprazole Magnesium), is a PPI that works by reducing hydrochloric acid in the stomach.
74. Even if used as directed, Defendants failed to adequately warn against the negative effects and risks associated with this product including, but not necessarily limited to, long term usage and the cumulative effects of long term usage.
75. During the period in which Prilosec has been sold in the United States, thousands of reported injuries have been submitted to the FDA in association with ingestion of Prilosec and other PPIs. Defendants have had notice of serious adverse health outcomes through case reports, clinical studies and post-market surveillance. Specifically, Defendants had received numerous case reports of kidney injuries in patients that had ingested Prilosec by as early as 1989. These reports of numerous kidney injuries put Defendants on notice as to the excessive risks of kidney injuries related to the use of Prilosec. However, Defendants took no action to inform Plaintiff or Plaintiff's physicians

---

<sup>1</sup> American Journal of Kidney Disease, VOLUME 75, ISSUE 4, P 497-507, APRIL 01, 2020, Ziyad Al-Aly, MD, Geetha Maddukuri, MD, and Yan Xie, MPH.

of this known risk. Instead, Defendants continued to represent that Prilosec did not pose any risks of kidney injuries.

76. As a result of Defendants' action and inactions, Plaintiff was injured due to his ingestion of Prilosec, which caused and will continue to cause Plaintiff various injuries and Damages, including but not limited to chronic kidney disease (CKD) and renal cell carcinoma (RCC).

77. Defendants knew of the significant risk of kidney damage that could result from long-term Prilosec use, but Defendants did not adequately and sufficiently warn consumers, including Plaintiff, his physician or the medical community in a timely manner.

78. Defendants took no action to inform Plaintiff or Plaintiff's physicians of this known risk. Instead, Defendants continued to represent that Prilosec did not pose any risks of kidney injuries.

79. Since the introduction of PPIs by pharmaceutical companies, numerous studies have linked PPI use to serious adverse health outcomes, including but not limited to, acute kidney injury ("AKI"), chronic kidney disease (CKD), and renal cell carcinoma (RCC).

80. Recent studies have shown the long term use of PPIs was independently associated with a 20% to 50% higher risk of incident chronic kidney disease ("CKD"), after adjusting for several potential confounding variables, including demographics, socioeconomic status, clinical measurements, prevalent comorbidities, and concomitant use of medications<sup>2</sup>.

---

<sup>2</sup> Benjamin Lazarus, MBBS1,2; Yuan Chen, MS1; Francis P. Wilson, MD, MS3; et al; JAMA Intern Med. 2016;176(2):238-246. doi:10.1001/jamainternmed.2015.7193.

81. CKD, also called chronic kidney failure, describes the gradual loss of kidney function.

Kidneys filter wastes and excess fluids from the blood, which are then excreted. When chronic kidney disease reaches an advanced stage, dangerous levels of fluid, electrolytes and wastes can build up in the body.

82. In the early stages of CKD, patients may have few signs or symptoms. CKD may not become apparent until kidney function is significantly impaired.

83. Treatment for CKD focuses on slowing the progression of the kidney damage, usually by attempting to control the underlying cause. CKD can progress to renal cell carcinoma without a patient even being aware of the damage to his or her kidneys. Early treatment is often key to avoiding the most negative outcomes.

84. CKD is associated with a substantially increased risk of death, cardiovascular events, and renal cell carcinoma.

85. CKD is identified by a blood test for creatinine, which is a breakdown product of muscle metabolism. Higher levels of creatinine indicate a lower glomerular filtration rate (eGFR) and as a result a decreased capability of the kidneys to excrete waste products.

86. CKD may also be detected through urinalysis in the early stages when creatinine levels may be normal. However, it may be necessary to employ a host of additional diagnostic tests, such as a kidney biopsy, medical imaging and blood tests, to fully understand the extent of CKD.

87. Screening of at-risk people is important because treatments exist that delay the progression of CKD. Making patients aware of the risks associated with PPIs coupled with screening can provide early warning signs of CKD allowing for the PPIs to be unprescribed.

88. Alternatives to PPIs are and were available that provide the same benefits but act through a different mechanism.
89. One alternative is H2 antagonists, also called H2 blockers, a class of medications that block the action of histamine at the histamine H2 receptors of the parietal cells in the stomach.
90. The higher risks of CKD are specific to PPI medications. The use of H2 receptor antagonists, which are prescribed for the same indication as PPIs, is not associated with CKD.
91. Similar findings were demonstrated for the outcome of AKI and collectively suggest that PPI use is an independent risk factor for CKD and for AKI.
92. In addition, a study has linked the acute kidney injuries caused by PPIs to a later increased risk of CKD and renal cell carcinoma. The study noted that PPI induced acute kidney disease is often subtle and slowly diagnosed. The delay in diagnosis causes damage to the kidney to be increased and the patient to have a higher risk of later developing CKD and RCC.
93. According to the National Kidney Foundation's Kidney Disease Outcome Quality Initiative guidelines, CKD's association with renal cell carcinoma is increasingly recognized<sup>3</sup>.
94. Defendants failed to adequately warn against the negative effects and risks associated with Prilosec. Defendants have totally failed to provide any warnings regarding CKD, AKI, or RCC.

---

<sup>3</sup> K/DOQI clinical practice guidelines for chronic kidney disease: evaluation, classification, and stratification. Am J Kidney Dis. 2002;39(Suppl 1):S1-266.

95. One study found that significantly higher incidences of cancer were found in patients with CKD. Researchers reported 3,220 incidents of cancer per 100,000 population. By contrast, there were only 645 incidents of cancer in the general non-CKD population<sup>4</sup>.
96. Glomerular filtration rate (GFR) and albuminuria are the main kidney measures used for detection, staging and management of acute and chronic kidney disease. GFR is a measure of kidney function; albuminuria is a marker of kidney damage.
97. In one study, researchers observed a 20% higher risk of lung, colon, **kidney**, and bladder cancer with each standard deviation increase of albuminuria readings<sup>5</sup>.
98. In yet another study, clinicians examined the connection between eGFR levels and the risk of incident cancer. The most common outcome was renal cancer<sup>6</sup>.
99. In omitting, concealing, and inadequately providing critical safety information regarding the use of Prilosec in order to induce its purchase and use, Defendants engaged in and continue to engage in conduct likely to mislead consumers including Plaintiffs. This conduct is fraudulent, unfair, and unlawful.
100. Defendants knew or should have known about the correlation between the use of Prilosec and the significantly increased risk of CKD, acute kidney injuries, and kidney cancer.
101. Despite clear knowledge that Prilosec causes a significantly increased risk of CKD, acute kidney injuries, and kidney cancer, Defendants continued to market and sell

---

<sup>4</sup> Tendulkar K, et al. Poster 276. Presented at: National Kidney Foundation Spring Clinical Meetings; May 8-12, 2019; Boston.

<sup>5</sup> Jorgensen L, Heuch I, Jenssen T, Jacobsen BK. Association of albuminuria and cancer incidence. J Am Soc Nephrol. 2008;19:992-998

<sup>6</sup> William T. Lowrance, Juan Ordoñez, Natalia Udaltsova, Paul Russo and Alan S. Go JASN October 2014, 25 (10) 2327-2334



Prilosec without warning consumers or healthcare providers of the significant risks of CKD and acute kidney injuries.

**FIRST CAUSE OF ACTION**  
**AS AGAINST THE DEFENDANTS**  
**(NEGLIGENCE)**

102. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.
103. Defendants had a duty to exercise reasonable care in the designing, researching, manufacturing, marketing, supplying, promoting, packaging, sale and/or distribution of Prilosec into the stream of commerce, including a duty to assure that the product would not cause users to suffer unreasonable, dangerous side effects.
104. Defendants failed to exercise ordinary care in the designing, researching, manufacturing, marketing, supplying, promoting, packaging, sale, testing, quality assurance, quality control, and/or distribution of Prilosec into interstate commerce in that Defendants knew or should have known that using Prilosec could proximately cause Plaintiff's injuries. Specifically, Defendants failed to meet their duty to use reasonable care in the testing, creating, designing, manufacturing, labeling, packaging, marketing, selling, and warning of Prilosec. Defendants are liable for acts and/or omissions amounting to negligence, gross negligence and/or malice including, but not limited to the following:

- a. Failure to adequately warn Plaintiff and Plaintiff's physicians of the known or reasonably foreseeable danger that plaintiff would suffer a serious injury or death by ingesting Prilosec;
  - b. Failure to adequately warn Plaintiff and Plaintiff's physicians of the known or reasonably foreseeable danger that Plaintiff would suffer a serious injury or death by ingesting Prilosec in unsafe doses;
  - c. Failure to use reasonable care in testing and inspecting Prilosec so as to ascertain whether or not it was safe for the purpose for which it was designed, manufactured and sold;
  - d. Failure to use reasonable care in implementing and/or utilizing a reasonably safe design in the manufacture of Prilosec;
  - e. Failure to use reasonable care in the process of manufacturing Prilosec in a reasonably safe condition for the use for which it was intended;
  - f. Failure to use reasonable care in the manner and method of warning Plaintiff and Plaintiff's physicians as to the danger and risks of using Prilosec in normal doses; and
  - g. Such further acts and/or omissions that may be proven at trial.
105. The above-described acts and/or omissions of Defendants were a direct and proximate cause of the severe, permanent and disabling injuries and resulting damages to Plaintiff.
106. The negligence of the Defendants, their agents, servants, and/or employees, included but was not limited to the following acts and/or omissions:

- a. Manufacturing, producing, promoting, formulating, creating, and/or designing Prilosec without thoroughly testing it;
- b. Manufacturing, producing, promoting, formulating, creating, and/or designing Prilosec without adequately testing it;
- c. Not conducting sufficient testing programs to determine whether or not Prilosec was safe for use; in that Defendants herein knew or should have known that Prilosec was unsafe and unfit for use by reason of the dangers to its users;
- d. Selling Prilosec without making proper and sufficient tests to determine the dangers to its users;
- e. Negligently failing to adequately and correctly warn the Plaintiff, the public, the medical and healthcare profession, and the FDA of the dangers of Prilosec;
- f. Failing to provide adequate instructions regarding safety precautions to be observed by users, handlers, and persons who would reasonably and foreseeably come into contact with, and more particularly, use, Prilosec;
- g. Failing to test Prilosec and/or failing to adequately, sufficiently and properly test Prilosec.
- h. Negligently advertising and recommending the use of Prilosec without sufficient knowledge as to its dangerous propensities;
- i. Negligently representing that Prilosec was safe for use for its intended purpose, when, in fact, it was unsafe;
- j. Negligently designing Prilosec in a manner which was dangerous to its users;
- k. Negligently manufacturing Prilosec in a manner which was dangerous to its users;
- l. Negligently producing Prilosec in a manner which was dangerous to its users;

- m. Negligently assembling Prilosec in a manner which was dangerous to its users;
  - n. Concealing information from the Plaintiff in knowing that Prilosec was unsafe, dangerous, and/or non-conforming with FDA regulations.
107. Defendants under-reported, underestimated and downplayed the serious dangers of Prilosec.
108. Defendants negligently compared the safety risk and/or dangers of Prilosec with other forms of treatment of peptic disorders which include gastroesophageal reflux disease (GERD), peptic ulcer disease, and nonsteroidal anti-inflammatory drug induced gastropathy.
109. Defendants were negligent in the designing, researching, supplying, manufacturing, promoting, packaging, distributing, testing, advertising, warning, marketing and sale of Prilosec in that they:
- a. Failed to use due care in designing and manufacturing Prilosec so as to avoid the aforementioned risks to individuals when Prilosec was used for treatment of peptic disorders which include gastroesophageal reflux disease (GERD), peptic ulcer disease, and nonsteroidal anti-inflammatory drug induced gastropathy;
  - b. Failed to accompany their product with proper and/or accurate warnings regarding all possible adverse side effects associated with the use of Prilosec;
  - c. Failed to accompany their product with proper warnings regarding all possible adverse side effects concerning the failure and/or malfunction of Prilosec;
  - d. Failed to accompany their product with accurate warnings regarding the risks of all possible adverse side effects concerning Prilosec;

- e. Failed to warn Plaintiff of the severity and duration of such adverse effects, as the warnings given did not accurately reflect the symptoms, or severity of the side effects;
  - f. Failed to conduct adequate testing, including pre-clinical and clinical testing and post-marketing surveillance to determine the safety of Prilosec;
  - g. Failed to warn Plaintiff, prior to actively encouraging the sale of Prilosec, either directly or indirectly, orally or in writing, about the need for more comprehensive, more regular medical monitoring than usual to ensure early discovery of potentially serious side effects;
  - h. Were otherwise careless and/or negligent.
110. Despite the fact that Defendants knew or should have known that Prilosec caused unreasonably dangerous side effects, Defendants continued to market, manufacture, distribute and/or sell Prilosec to consumers, including the Plaintiff.
111. Defendants knew or should have known that consumers such as the Plaintiff would foreseeably suffer injury as a result of Defendants' failure to exercise ordinary care, as set forth above.
112. Defendants' negligence was the proximate cause of Plaintiff's injuries, harm and economic loss which Plaintiffs suffered and/or will continue to suffer.
113. As a result of the foregoing acts and omissions, the Plaintiff was caused to suffer serious and dangerous side effects including, Chronic Kidney Disease, Renal Cell Carcinoma, surgery to remove a large tumor from his kidney, loss of 15% of kidney, a painful hernia caused by the cancer removal, additional surgeries to repair the hernia,, which is permanent and lasting in nature, physical pain and mental anguish, including

diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications to prevent a CANCER recurrence, additional episodes of INTERNAL BLEEDING and potential TEARS to his muscles and stomach lining.

114. As a result of the foregoing acts and omissions the Plaintiff requires and/or will require more health care and services while incurring medical, health, incidental and related expenses. Plaintiff is informed and believes and further alleges that Plaintiff will in the future be required to obtain further medical and/or hospital care, attention, and services.
115. By reason of the foregoing, Plaintiff has been damaged as against the Defendants in the sum of ONE HUNDRED MILLION DOLLARS (\$100,000,000.00).

**SECOND CAUSE OF ACTION**  
**AS AGAINST THE DEFENDANTS**  
**(STRICT PRODUCTS LIABILITY)**

116. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.
117. At all times herein mentioned, the Defendants designed, researched, manufactured, tested, advertised, promoted, marketed, sold, distributed, and/or have recently acquired the Defendants who have designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed Prilosec as hereinabove described that was used by the Plaintiff.
118. That Prilosec was expected to and did reach the usual consumers, handlers, and persons coming into contact with said product without substantial change in the condition

in which it was produced, manufactured, sold, distributed, and marketed by the Defendants.

119. At those times, Prilosec was in an unsafe, defective, and inherently dangerous condition, which was dangerous to users, and in particular, the Plaintiff herein.

120. The Prilosec designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants was defective in design or formulation in that, when it left the hands of the manufacturer and/or suppliers, the foreseeable risks exceeded the benefits associated with the design or formulation of Prilosec.

121. The Prilosec designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants was defective in design and/or formulation, in that, when it left the hands of the Defendants manufacturers and/or suppliers, it was unreasonably dangerous, and it was more dangerous than an ordinary consumer would expect.

122. At all times herein mentioned, Prilosec was in a defective condition and unsafe, and Defendants knew or had reason to know that said product was defective and unsafe, especially when used in the form and manner as provided by the Defendants.

123. Defendants knew, or should have known that at all times herein mentioned its Prilosec was in a defective condition, and was and is inherently dangerous and unsafe.

124. At the time of the Plaintiff's use of Prilosec, Prilosec was being used for the purposes and in a manner normally intended for the treatment of peptic disorders which include gastroesophageal reflux disease (GERD), peptic ulcer disease, and nonsteroidal antiinflammatory drug induced gastropathy.

125. Defendants with this knowledge voluntarily designed its Prilosec in a dangerous condition for use by the public, and in particular the Plaintiff.
126. Defendants had a duty to create a product that was not unreasonably dangerous for its normal, intended use.
127. Defendants created a product unreasonably dangerous for its normal, intended use.
128. The Prilosec designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants was manufactured defectively in that Prilosec left the hands of Defendants in a defective condition and was unreasonably dangerous to its intended users.
129. The Prilosec designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants reached their intended users in the same defective and unreasonably dangerous condition in which the Defendants' Prilosec was manufactured.
130. Defendants designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed a defective product which created an unreasonable risk to the health of consumers and to the Plaintiff in particular, and Defendants are therefore strictly liable for the injuries sustained by the Plaintiff.
131. The Plaintiff could not, by the exercise of reasonable care, have discovered Prilosec's defects herein mentioned and perceived its danger.
132. Prilosec was designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants was defective due to inadequate warnings or instructions as the Defendants knew or should have known that the product created a risk of serious and dangerous side effects including, kidney injuries, AKI, CKD, AND



RCC, as well as other severe and personal injuries which are permanent and lasting in nature and the Defendants failed to adequately warn of said risk.

133. Prilosec was designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants was defective due to inadequate warnings and/or inadequate testing.
134. Prilosec was designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants was defective due to inadequate post-marketing surveillance and/or warnings because, after Defendants knew or should have known of the risks of serious side effects including, kidney injuries, AKI, CKD, AND RCC, as well as other severe and permanent health consequences from Prilosec, they failed to provide adequate warnings to users or consumers of the product, and continued to improperly advertise, market and/or promote their product, Prilosec.
135. By reason of the foregoing, the Defendants have become strictly liable in tort to the Plaintiff for the manufacturing, marketing, promoting, distribution, and selling of a defective product, Prilosec.
136. Defendants' defective design, manufacturing defect, and inadequate warnings of Prilosec were acts that amount to willful, wanton, and/or reckless conduct by Defendants.
137. That said defects in Defendants' drug Prilosec were a substantial factor in causing Plaintiff's injuries.
138. As a result of the foregoing acts and omissions, the Plaintiff was caused to suffer serious and dangerous side effects including, Chronic Kidney Disease, Renal Cell Carcinoma, surgery to remove a large tumor from his kidney, loss of 15% of kidney, a painful hernia caused by the cancer removal, additional surgeries to repair the hernia,,

which is permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications to prevent a CANCER recurrence, additional episodes of INTERNAL BLEEDING and potential TEARS to his muscles and stomach lining.

139. As a result of the foregoing acts and omissions the Plaintiff requires and/or will require more health care and services and did incur medical, health, incidental and related expenses. Plaintiff is informed and believes and further alleges that Plaintiff will in the future be required to obtain further medical and/or hospital care, attention, and services.
140. By reason of the foregoing, Plaintiff has been damaged as against the Defendants in the sum of ONE HUNDRED MILLION DOLLARS (\$100,000,000.00)

**THIRD CAUSE OF ACTION**  
**AS AGAINST THE DEFENDANTS**  
**(BREACH OF EXPRESS WARRANTY)**

141. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.
142. Defendants expressly warranted that Prilosec was safe and well accepted by users.
143. Prilosec does not conform to these express representations because Prilosec is not safe and has numerous serious side effects, many of which were not accurately warned about by Defendants. As a direct and proximate result of the breach of said warranties, Plaintiff suffered and/or will continue to suffer severe and permanent personal injuries, harm and economic loss.
144. Plaintiff did rely on the express warranties of the Defendants herein.

145. Members of the medical community, including physicians and other healthcare professionals, relied upon the representations and warranties of the Defendants for use of Prilosec in recommending, prescribing, and/or dispensing Prilosec.
146. The Defendants herein breached the aforesaid express warranties, as their drug Prilosec was defective.
147. Defendants expressly represented to Plaintiff, his physicians, healthcare providers, and/or the FDA that Prilosec was safe and fit for use for the purposes intended, that it was of merchantable quality, that it did not produce any dangerous side effects in excess of those risks associated with other forms for treatment of peptic disorders which include gastroesophageal reflux disease (GERD), peptic ulcer disease, and nonsteroidal antiinflammatory drug induced gastropathy, that the side effects it did produce were accurately reflected in the warnings and that it was adequately tested and fit for its intended use.
148. Defendants knew or should have known that, in fact, said representations and warranties were false, misleading and untrue in that Prilosec was not safe and fit for the use intended, and, in fact, produced serious injuries to the users that were not accurately identified and represented by Defendants.
149. As a result of the foregoing acts and omissions, the Plaintiff was caused to suffer serious and dangerous side effects including, Chronic Kidney Disease, Renal Cell Carcinoma, surgery to remove a large tumor from his kidney, loss of 15% of kidney, a painful hernia caused by the cancer removal, additional surgeries to repair the hernia,, which is permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment,

monitoring and/or medications to prevent a CANCER recurrence, additional episodes of INTERNAL BLEEDING and potential TEARS to his muscles and stomach lining.

150. By reason of the foregoing, Plaintiff has been severely and permanently injured, and will require more constant and continuous medical monitoring and treatment than prior to Plaintiff's use of Defendants' Prilosec drug.

151. As a result of the foregoing acts and omissions the Plaintiff requires and/or will require more health care and services and incur medical, health, incidental and related expenses. Plaintiff is informed and believes and further alleges that Plaintiff will in the future be required to obtain further medical and/or hospital care, attention, and services. By reason of the foregoing, Plaintiff has been damaged as against the Defendants in the sum of ONE HUNDRED MILLION DOLLARS (\$100,000,000.00).

**FOURTH CAUSE OF ACTION**  
**AS AGAINST THE DEFENDANTS**  
**(BREACH OF IMPLIED WARRANTIES)**

152. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

153. At all times herein mentioned, the Defendants manufactured, compounded, portrayed, distributed, recommended, merchandised, advertised, promoted and sold Prilosec and/or have recently acquired the Defendants who have manufactured, compounded, portrayed, distributed, recommended, merchandised, advertised, promoted and sold Prilosec for the treatment of peptic disorders which include gastroesophageal reflux disease (GERD), peptic ulcer disease, and nonsteroidal anti-inflammatory drug induced gastropathy.

154. At the time Defendants marketed, sold, and distributed Prilosec for use by Plaintiff, Defendants knew of the use for which Prilosec was intended and impliedly warranted the product to be of merchantable quality and safe and fit for such use.
155. The Defendants impliedly represented and warranted to the users of Prilosec and their physicians, healthcare providers, and/or the FDA that Prilosec was safe and of merchantable quality and fit for the ordinary purpose for which said product was to be used.
156. That said representations and warranties aforementioned were false, misleading, and inaccurate in that Prilosec was unsafe, unreasonably dangerous, improper, not of merchantable quality, and defective.
157. Plaintiff, and/or members of the medical community and/or healthcare professionals did rely on said implied warranty of merchantability of fitness for a particular use and purpose.
158. Plaintiff and Plaintiff's physicians and healthcare professionals reasonably relied upon the skill and judgment of Defendants as to whether Prilosec was of merchantable quality and safe and fit for its intended use.
159. Prilosec was injected into the stream of commerce by the Defendants in a defective, unsafe, and inherently dangerous condition and the products and materials were expected to and did reach users, handlers, and persons coming into contact with said products without substantial change in the condition in which they were sold.
160. The Defendants herein breached the aforesaid implied warranties, as their drug Prilosec was not fit for its intended purposes and uses.

161. As a result of the foregoing acts and omissions, the Plaintiff was caused to suffer serious and dangerous side effects including, Chronic Kidney Disease, Renal Cell Carcinoma, surgery to remove a large tumor from his kidney, loss of 15% of kidney, a painful hernia caused by the cancer removal, additional surgeries to repair the hernia,, which is permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications to prevent a CANCER recurrence, additional episodes of INTERNAL BLEEDING and potential TEARS to his muscles and stomach lining.
162. By reason of the foregoing, Plaintiff has been severely and permanently injured, and will require more constant and continuous medical monitoring and treatment than prior to Plaintiff's use of Defendants' Prilosec drug.
163. As a result of the foregoing acts and omissions the Plaintiff requires and/or will require more health care and services and incur medical, health, incidental and related expenses. Plaintiff is informed and believes and further alleges that Plaintiff will in the future be required to obtain further medical and/or hospital care, attention, and services.
164. By reason of the foregoing, Plaintiff has been damaged as against the Defendants in the sum of ONE HUNDRED MILLION DOLLARS (\$100,000,000.00).

**FIFTH CAUSE OF ACTION**  
**AS AGAINST THE DEFENDANTS**  
**(FRAUDULENT MISREPRESENTATION)**

165. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

166. The Defendants falsely and fraudulently represented to the medical and healthcare community, and to the Plaintiff, and/or the FDA, and the public in general, that said product, Prilosec had been tested and was found to be safe and/or effective for treatment of peptic disorders which include gastroesophageal reflux disease (GERD), peptic ulcer disease, and nonsteroidal anti-inflammatory drug induced gastropathy.
167. These representations made by Defendants were, in fact, false.
168. When said representations were made by Defendants, they knew those representations to be false and it willfully, wantonly and recklessly disregarded whether the representations were true.
169. These representations were made by said Defendants with the intent of defrauding and deceiving the Plaintiff, the public in general, and the medical and healthcare community in particular, and were made with the intent of inducing the public in general, and the medical and healthcare community in particular, to recommend, prescribe, dispense and/or purchase said product, Prilosec, for treatment of peptic disorders which include gastroesophageal reflux disease (GERD), peptic ulcer disease, and nonsteroidal anti-inflammatory drug induced gastropathy, all of which evinced a callous, reckless, willful, depraved indifference to the health, safety and welfare of the Plaintiff herein.
170. At the time the aforesaid representations were made by the Defendants and, at the time the Plaintiff used Prilosec, the Plaintiff was unaware of the falsity of said representations and reasonably believed them to be true.
171. In reliance upon said representations, the Plaintiff was induced to and did use Prilosec, thereby sustaining severe and permanent personal injuries, and/or being at an increased risk of sustaining severe and permanent personal injuries in the future.

172. Said Defendants knew and were aware or should have been aware that Prilosec had not been sufficiently tested, was defective in nature, and/or that it lacked adequate and/or sufficient warnings.
173. Defendants knew or should have known that Prilosec had a potential to, could, and would cause severe and grievous injury to the users of said product, and that it was inherently dangerous in a manner that exceeded any purported, inaccurate, and/or down-played warnings.
174. Defendants brought Prilosec to the market, and acted fraudulently, wantonly and maliciously to the detriment of the Plaintiff.
175. As a result of the foregoing acts and omissions, the Plaintiff was caused to suffer serious and dangerous side effects including, Chronic Kidney Disease, Renal Cell Carcinoma, surgery to remove a large tumor from his kidney, loss of 15% of kidney, a painful hernia caused by the cancer removal, additional surgeries to repair the hernia,, which is permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications to prevent a CANCER recurrence, additional episodes of INTERNAL BLEEDING and potential TEARS to his muscles and stomach lining.
176. As a result of the foregoing acts and omissions the Plaintiff requires and/or will require more health care and services and incur medical, health, incidental and related expenses. Plaintiff is informed and believes and further alleges that Plaintiff will in the future be required to obtain further medical and/or hospital care, attention, and services.
177. By reason of the foregoing, Plaintiff has been damaged as against the Defendants in the sum of ONE HUNDRED MILLION DOLLARS (\$100,000,000.00).



**SIXTH CAUSE OF ACTION**  
**AS AGAINST THE DEFENDANTS**  
**(FRAUDULENT CONCEALMENT)**

178. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.
179. At all times during the course of dealing between Defendants and Plaintiff, and/or Plaintiff's healthcare providers, and/or the FDA, Defendants misrepresented the safety of Prilosec for its intended use.
180. Defendants knew or were reckless in not knowing that its representations were false.
181. In representations to Plaintiff, and/or Plaintiff's healthcare providers, and/or the FDA, Defendants fraudulently concealed and intentionally omitted the following material information:
- a. that Prilosec was not as safe as other forms of treatment for peptic disorders which include gastroesophageal reflux disease (GERD), peptic ulcer disease, and nonsteroidal antiinflammatory drug induced gastropathy;
  - b. that the risks of adverse events with Prilosec were higher than those with other forms of treatment of peptic disorders which include gastroesophageal reflux disease (GERD), peptic ulcer disease, and nonsteroidal anti-inflammatory drug induced gastropathy;
  - c. that the risks of adverse events with Prilosec were not adequately tested and/or known by Defendants;

- d. that Defendants were aware of dangers in Prilosec, in addition to and above and beyond those associated with other forms of treatment of peptic disorders which include gastroesophageal reflux disease (GERD), peptic ulcer disease, and nonsteroidal antiinflammatory drug induced gastropathy;
  - e. that Prilosec was defective, and that it caused dangerous side effects, including but not limited to kidney injuries;
  - f. that patients needed to be monitored more regularly than normal while using Prilosec;
  - g. that Prilosec was manufactured negligently;
  - h. that Prilosec was manufactured defectively;
  - i. that Prilosec was manufactured improperly;
  - j. that Prilosec was designed negligently;
  - k. that Prilosec was designed defectively; and
  - l. that Prilosec was designed improperly.
182. Defendants were under a duty to disclose to Plaintiff, and Plaintiff's physicians, hospitals, healthcare providers, and/or the FDA the defective nature of Prilosec, including but not limited to the heightened risks of kidney injury, including AKI, CKD, and RCC.
183. Defendants had sole access to material facts concerning the defective nature of the product and its propensity to cause serious and dangerous side effects, and hence, cause damage to persons who used Prilosec, including the Plaintiff, in particular.
184. Defendants' concealment and omissions of material facts concerning, inter alia, the safety of Prilosec was made purposefully, willfully, wantonly, and/or recklessly, to mislead Plaintiff, and Plaintiff's physicians, hospitals and healthcare providers into

reliance, continued use of Prilosec, and actions thereon, and to cause them to purchase, prescribe, and/or dispense Prilosec and/or use the product.

185. Defendants knew that Plaintiff, and Plaintiff's physicians, hospitals, healthcare providers, and/or the FDA had no way to determine the truth behind Defendants' concealment and omissions, and that these included material omissions of facts surrounding Prilosec, as set forth herein.

186. Plaintiff, as well as Plaintiff's doctors, healthcare providers, and/or hospitals reasonably relied on facts revealed which negligently, fraudulently and/or purposefully did not include facts that were concealed and/or omitted by Defendants.

187. As a result of the foregoing acts and omissions, the Plaintiff was caused to suffer serious and dangerous side effects including, Chronic Kidney Disease, Renal Cell Carcinoma, surgery to remove a large tumor from his kidney, loss of 15% of kidney, a painful hernia caused by the cancer removal, additional surgeries to repair the hernia,, which is permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications to prevent a CANCER recurrence, additional episodes of INTERNAL BLEEDING and potential TEARS to his muscles and stomach lining.

188. As a result of the foregoing acts and omissions the Plaintiff requires and/or will require more health care and services and did incur medical, health, incidental and related expenses. Plaintiff is informed and believes and further alleges that Plaintiff will in the future be required to obtain further medical and/or hospital care, attention, and services.

189. By reason of the foregoing, Plaintiff has been damaged as against the Defendants in the sum of ONE HUNDRED MILLION DOLLARS (\$100,000,000.00).

**SEVENTH CAUSE OF ACTION**  
**AS AGAINST THE DEFENDANTS**  
**(NEGLIGENT MISREPRESENTATION)**

190. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.
191. Defendants had a duty to represent to the medical and healthcare community, and to the Plaintiff, the FDA and the public in general that said product, Prilosec, had been tested and found to be safe and effective for treatment of peptic disorders which include gastroesophageal reflux disease (GERD), peptic ulcer disease, and nonsteroidal anti-inflammatory drug induced gastropathy.
192. The representations made by Defendants were, in fact, false.
193. Defendants failed to exercise ordinary care in the representation of Prilosec, while involved in its manufacture, sale, testing, quality assurance, quality control, and/or distribution of said product into interstate commerce, in that Defendants negligently misrepresented Prilosec's high risk of unreasonable, dangerous side effects.
194. Defendants breached their duty in representing Prilosec's serious side effects to the medical and healthcare community, to the Plaintiff, the FDA and the public in general.
195. As a result of the foregoing acts and omissions, the Plaintiff was caused to suffer serious and dangerous side effects including, Chronic Kidney Disease, Renal Cell Carcinoma, surgery to remove a large tumor from his kidney, loss of 15% of kidney, a painful hernia caused by the cancer removal, additional surgeries to repair the hernia,, which is permanent and lasting in nature, physical pain and mental anguish, including

diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications to prevent a CANCER recurrence, additional episodes of INTERNAL BLEEDING and potential TEARS to his muscles and stomach lining.

196. As a result of the foregoing acts and omissions the Plaintiff requires and/or will require more health care and services and incur medical, health, incidental and related expenses. Plaintiff is informed and believes and further alleges that Plaintiff will in the future be required to obtain further medical and/or hospital care, attention, and services.
197. By reason of the foregoing, Plaintiff has been damaged as against the Defendants in the sum of ONE HUNDRED MILLION DOLLARS (\$100,000,000.00).

**EIGHTH CAUSE OF ACTION**  
**AS AGAINST THE DEFENDANTS**  
**(FRAUD AND DECEIT)**

198. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.
199. Defendants conducted research and used Prilosec as part of their research.
200. As a result of Defendants' research and testing, or lack thereof, Defendants blatantly and intentionally distributed false information, including but not limited to assuring the public, the Plaintiff, Plaintiff's doctors, hospitals, healthcare professionals, and/or the FDA that Prilosec was safe and effective for treatment of peptic disorders which include gastroesophageal reflux disease (GERD), peptic ulcer disease, and nonsteroidal anti-inflammatory drug induced gastropathy.

201. As a result of Defendants' research and testing, or lack thereof, Defendants intentionally omitted certain results of testing and research to the public, healthcare professionals, and/or the FDA, including the Plaintiff.
202. Defendants had a duty when disseminating information to the public to disseminate truthful information and a parallel duty not to deceive the public and the Plaintiff, as well as Plaintiff's respective healthcare providers and/or the FDA.
203. The information distributed to the public, the FDA, and the Plaintiff by Defendants, including but not limited to reports, press releases, advertising campaigns, television commercials, print ads, magazine ads, billboards, and all other commercial media contained material representations of fact and/or omissions.
204. The information distributed to the public, the FDA, and the Plaintiff by Defendants intentionally included representations that Defendants' drug Prilosec was safe and effective for use for treatment of peptic disorders which include gastroesophageal reflux disease (GERD), peptic ulcer disease, and nonsteroidal anti-inflammatory drug induced gastropathy.
205. The information distributed to the public, the FDA, and the Plaintiff, by Defendants intentionally included representations that Defendants' drug Prilosec carried the same risks, hazards, and/or dangers as other forms of treatment for peptic disorders which include gastroesophageal reflux disease (GERD), peptic ulcer disease, and nonsteroidal anti-inflammatory drug induced gastropathy.
206. The information distributed to the public, the FDA, and the Plaintiff, by Defendants intentionally included false representations that Prilosec was not injurious to the health and/or safety of its intended users.

207. The information distributed to the public, the FDA, and the Plaintiff, by Defendants intentionally included false representations that Prilosec was as potentially injurious to the health and/or safety of its intended users as other forms of treatment for peptic disorders which include gastroesophageal reflux disease (GERD), peptic ulcer disease, and nonsteroidal anti-inflammatory drug induced gastropathy.
208. These representations were all false and misleading.
209. Upon information and belief, Defendants intentionally suppressed, ignored and disregarded test results not favorable to the Defendants, and results that demonstrated that Prilosec was not safe as a means of treatment for peptic disorders which include gastroesophageal reflux disease (GERD), peptic ulcer disease, and nonsteroidal antiinflammatory drug induced gastropathy.
210. Defendants intentionally made material representations to the FDA and the public, including the medical profession, and the Plaintiff, regarding the safety of Prilosec, specifically but not limited to Prilosec not having dangerous and serious health and/or safety concerns.
211. Defendants intentionally made material representations to the FDA and the public in general, including the medical profession, and the Plaintiff, regarding the safety of Prilosec, specifically but not limited to Prilosec being a safe means for treatment of peptic disorders which include gastroesophageal reflux disease (GERD), peptic ulcer disease, and nonsteroidal antiinflammatory drug induced gastropathy.
212. That it was the purpose of Defendants in making these representations to deceive and defraud the public, the FDA, and/or the Plaintiff, to gain the confidence of the public, healthcare professionals, the FDA, and/or the Plaintiff, to falsely ensure the quality and

fitness for use of Prilosec induce the public, and/or the Plaintiff to purchase, request, dispense, prescribe, recommend, and/or continue to use Prilosec.

213. Defendants made the aforementioned false claims and false representations with the intent of convincing the public, healthcare professionals, the FDA, and/or the Plaintiff that Prilosec was fit and safe for treatment of peptic disorders which include gastroesophageal reflux disease (GERD), peptic ulcer disease, and nonsteroidal anti-inflammatory drug induced gastropathy.

214. Defendants made the aforementioned false claims and false representations with the intent of convincing the public, healthcare professionals, the FDA, and/or the Plaintiff that Prilosec was fit and safe for treatment of peptic disorders which include gastroesophageal reflux disease (GERD), peptic ulcer disease, and nonsteroidal anti-inflammatory drug induced gastropathy.

215. That Defendants made claims and representations in its documents submitted to the FDA, to the public, to healthcare professionals, and the Plaintiff that Prilosec did not present serious health and/or safety risks.

216. That Defendants made claims and representations in its documents submitted to the FDA, to the public, to healthcare professionals, and the Plaintiff that Prilosec did not present health and/or safety risks greater than other oral forms for treatment of peptic disorders which include gastroesophageal reflux disease (GERD), peptic ulcer disease, and nonsteroidal antiinflammatory drug induced gastropathy.

217. That these representations and others made by Defendants were false when made, and/or were made with a pretense of actual knowledge when knowledge did not actually exist, and/or were made recklessly and without regard to the actual facts.



218. That these representations and others, made by Defendants, were made with the intention of deceiving and defrauding the Plaintiff, including his respective healthcare professionals and/or the FDA, and were made in order to induce the Plaintiff and/or his respective healthcare professionals to rely upon misrepresentations and caused the Plaintiff to purchase, use, rely on, request, dispense, recommend, and/or prescribe Prilosec.
219. That Defendants, recklessly and intentionally falsely represented the dangerous and serious health and/or safety concerns of Prilosec to the public at large, the Plaintiff in particular, for the purpose of influencing the marketing of a product known to be dangerous and defective and/or not as safe as other alternatives, including other forms of treatment of peptic disorders which include gastroesophageal reflux disease (GERD), peptic ulcer disease, and nonsteroidal anti-inflammatory drug induced gastropathy.
220. That Defendants willfully and intentionally failed to disclose the material facts regarding the dangerous and serious safety concerns of Prilosec by concealing and suppressing material facts regarding the dangerous and serious health and/or safety concerns of Prilosec.
221. That Defendants willfully and intentionally failed to disclose the truth, failed to disclose material facts and made false representations with the purpose and design of deceiving and lulling the Plaintiff, as well as his respective healthcare professionals into a sense of security so that Plaintiff would rely on the representations and purchase, use and rely on Prilosec and/or that Plaintiff's respective healthcare providers would dispense, prescribe, and/or recommend the same.

222. Defendants, through their public relations efforts, which included but were not limited to the public statements and press releases, knew or should have known that the public, including the Plaintiff, as well as Plaintiff's respective healthcare professionals would rely upon the information being disseminated.
223. Defendants utilized direct to consumer advertising to market, promote, and/or advertise Prilosec.
224. That the Plaintiff and/or his respective healthcare professionals did in fact rely on and believe the Defendants' representations to be true at the time they were made and relied upon the representations as well as the superior knowledge of treatment of peptic disorders which include gastroesophageal reflux disease (GERD), peptic ulcer disease, and nonsteroidal anti-inflammatory drug induced gastropathy.
225. That at the time the representations were made, the Plaintiff and/or his respective healthcare providers did not know the truth with regard to the dangerous and serious health and/or safety concerns of Prilosec.
226. That the Plaintiff did not discover the true facts with respect to the dangerous and serious health and/or safety concerns, and the false representations of Defendants, nor could the Plaintiff with reasonable diligence have discovered the true facts.
227. That had the Plaintiff known the true facts with respect to the dangerous and serious health and/or safety concerns of Prilosec, Plaintiff would not have purchased, used and/or relied on Defendants' drug Prilosec.
228. That the Defendants' aforementioned conduct constitutes fraud and deceit, and was committed and/or perpetrated willfully, wantonly and/or purposefully on the Plaintiff.

229. As a result of the foregoing acts and omissions, the Plaintiff was caused to suffer serious and dangerous side effects including, Chronic Kidney Disease, Renal Cell Carcinoma, surgery to remove a large tumor from his kidney, loss of 15% of kidney, a painful hernia caused by the cancer removal, additional surgeries to repair the hernia,, which is permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications to prevent a CANCER recurrence, additional episodes of INTERNAL BLEEDING and potential TEARS to his muscles and stomach lining.
230. As a result of the foregoing acts and omissions the Plaintiff requires and/or will require more health care and services and incur medical, health, incidental and related expenses. Plaintiff is informed and believes and further alleges that Plaintiff will in the future be required to obtain further medical and/or hospital care, attention, and services.
231. By reason of the foregoing, Plaintiff has been damaged as against the Defendants in the sum of ONE HUNDRED MILLION DOLLARS (\$100,000,000.00).

#### **PRAYER FOR RELIEF**

WHEREFORE, Plaintiff demands judgment against the Defendants on each of the above-referenced claims and Causes of Action and as follows:

1. Awarding compensatory damages to Plaintiffs for past and future damages, including but not limited to pain and suffering for severe and permanent personal injuries sustained by the Plaintiff, health care costs, medical monitoring, together with interest and costs as provided by law;

2. Punitive and/or exemplary damages for the wanton, willful, fraudulent, reckless acts of the Defendants who demonstrated a complete disregard and reckless indifference for the safety and welfare of the general public and to the Plaintiff in an amount sufficient to punish Defendants and deter future similar conduct;
3. Awarding Plaintiff reasonable attorneys' fees;
4. Awarding Plaintiff the costs of these proceedings; and
5. Such other and further relief as this Court deems just and proper.

Dated: New York, New York  
May 7, 2021

BY: \_\_\_\_\_/S  
Kenneth E. Belkin, Esq. (KB-0080)  
225 Broadway, Suite 715  
New York, New York 10007  
c: (718) 724-3466  
f: (212) 566-8165  
e: kb@belkinlaw.com